IN THE MISSOURI COURT OF APPEALS
WESTERN DISTRICT

J.W.,	)	
	)	
Appellant,	)	
	)	
v.	)	
	)	
BAYER CORP., ET AL.,	)	Opinion filed: December 5, 2017
	)	
Respondent.	)	

APPEAL FROM THE CIRCUIT COURT OF [redacted] COUNTY, MISSOURI
THE HONORABLE [redacted], JUDGE

Before Division Four: [redacted]

J.W. brought this cause of action in the Circuit Court of [redacted] County alleging fourteen separate claims against Bayer Corp. (Bayer) related to its Essure contraceptive device along with a variety of counts against her treating physicians. Bayer filed a Motion to Dismiss on the basis that the claims directed against it were preempted under federal law which was granted by the trial court. J.W. now appeals arguing that the trial court erred in dismissing those claims on preemption grounds and in not granting her leave to file an amended petition. We affirm in part and reverse and remand in part.

Factual and Procedural Background

J.W. became pregnant with her fifth child sometime in late 2012. After consulting with her physicians, she made the determination to undergo a tubal ligation in conjunction with the

delivery.[1] However, in late April of 2013, J.W.'s physicians determined the umbilical cord had prolapsed around her fetus and she required an immediate caesarian section. Due to the emergency nature of the caesarian section, the tubal ligation was not performed. Following the birth, her physicians recommended J.W. consider using Essure as an alternative to tubal ligation. Essure is a medical device manufactured and sold by Bayer that is implanted in a woman's fallopian tube for the purpose of causing inflammation and promoting the growth of scar tissue. This scar tissue blocks the fallopian tube, thereby achieving sterilization. After considering the recommendations of her physicians and reviewing the information provided on the Essure website, J.W. agreed to undergo the Essure procedure.

During the procedure to place the Essure device, J.W. began to experience severe abdominal pain and requested her physicians stop. As a result, the procedure was abandoned after only one of the two devices was inserted. J.W. continued to experience significant pain following the procedure and, after several months, requested her physicians remove the Essure device. An x-ray performed during the attempt to remove the Essure device revealed that it had broken apart and perforated J.W.'s uterine wall. Consequently, pieces of the Essure device were left in J.W.'s body. J.W. continued to experience pain and underwent further surgery to remove one of her fallopian tubes along with a hysterectomy.

On July 29, 2015, J.W. filed a petition alleging multiple claims against Bayer as well as additional claims directed at several of her physicians. One month after filing her initial petition, J.W. filed an amended petition that included the same causes of action against Bayer. Bayer thereafter filed a Motion to Dismiss arguing, among other things, that all of J.W.'s claims were expressly or impliedly preempted by federal law. After extensive briefing, the trial court

[1] Tubal ligation is a method of permanent female sterilization.

heard oral argument before taking the matter under advisement. On March 17, 2016, the trial court issued an order granting Bayer's Motion to Dismiss finding all of the claims asserted against Bayer were preempted under federal law.[2] J.W. subsequently filed Plaintiff's Motion to Amend Judgment that included a request for leave to amend her petition along with a proposed Second Amended Petition, which the trial court did not grant. J.W. appeals.

Discussion

J.W.'s First Amended Petition included fourteen counts directed against Bayer: (Count 1) violation of the Missouri Merchandising Practices Act (MMPA), (Count 2) fraudulent misrepresentation, (Count 3) negligent misrepresentation, (Count 4) breach of express warranties, (Count 5) breach of implied warranty of merchantability, (Count 6) negligence *per se*, (Count 7) strict product liability — defective manufacturing, (Count 8) negligent manufacturing, (Count 9) strict products liability for failure to warn — off-label use, (Count 10) failure to warn — post premarket approval risks, (Count 11) negligent training, (Count 12) negligently supplying a product for use, (Count 16) civil conspiracy, and (Count 17) *res ipsa loquitur*. The trial court found that each of these claims were expressly or impliedly preempted by the federal Medical Device Amendment of 1976, 21 U.S.C. §360c, *et seq.*, and dismissed each with prejudice. J.W.'s first point on appeal argues that the trial court erred in reaching this conclusion.

[2] The trial court's initial order did not include the word judgment. At Bayer's request, the trial court added the word judgment to its previous order, which the trial court signed on July 19, 2016. In addition, for a judgment to be final and appealable, it "normally must resolve all issues, leaving nothing for future determination." *Kinney v. Schneider National Carriers, Inc.*, 213 S.W.3d 179, 182 (Mo. App. W.D. 2007). Under Supreme Court Rule 74.01, where there are multiple claims or parties, the trial court can certify a partial judgment as final if it determines that there is no just reason for delay, which the trial court did in this case. *Id.* However, "[t]he trial court's certification that 'there is no just reason for delay' is not conclusive and we review the partial judgment to see if it qualifies as a final judgment." *Id.* We are satisfied that the judgment dismissing all counts against Bayer on preemption grounds constitutes a "distinct judicial unit" reviewable on appeal. *See id.* ("A judgment that dismisses one of two defendants on the basis of a defense available to only the dismissed defendant constitutes a 'distinct judicial unit' reviewable on appeal.").

We review the granting of a motion to dismiss *de novo*. *Armstrong-Trotwood, LLC v. State Tax Commission,* 516 S.W.3d 830, 835 (Mo. banc 2017). We assume all facts alleged in the petition are true and liberally construe all reasonable inferences in favor of the plaintiff. *Smith v. Humane Soc'y of United States*, 519 S.W.3d 789, 798 (Mo. banc 2017). "[T]he petition is reviewed in an almost academic manner, to determine if the facts alleged meet the elements of a recognized cause of action, or of a cause that might be adopted in that case." *Id.* (quoting *Nazeri v. Mo. Valley C.*, 860 S.W.2d 303, 306 (Mo. banc 1993)).

Background regarding the Medical Device Amendment of 1976

"The Federal Food, Drug, and Cosmetic Act (FDCA) has long required FDA approval for the introduction of new drugs into the market." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008) (internal citations omitted). The same cannot be said of medical devices, however, which the act initially "did not authorize any control over." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996). Instead, "the introduction of new medical devices was left largely for the States to supervise as they saw fit." *Riegel*, 552 U.S. at 315. However, this changed following the highly publicized failure of several medical devices in the 1970's, the most notable being the Dalkon Shield intrauterine contraceptive device. *See Riegel*, 552 U.S. at 315; *Lohr*, 518 U.S. at 476. In response to these failures, Congress passed the Medical Devices Amendment of 1976, 21 U.S.C. §360c, *et seq.*, (MDA), which established a comprehensive scheme of federal oversight regarding the introduction of new medical devices. *Riegel*, 552 U.S. at 316.

Under the MDA, medical devices are divided into one of three classes. "Devices that present no unreasonable risk of illness or injury are designated Class I and are subject only to minimal regulation by 'general controls.'" *Lohr*, 518 U.S. at 476–77 (citing 21 U.S.C. § 360c(a)(1)(A)). These devices include such things as elastic bandages and examination gloves.

Riegel, 552 U.S. at 316. "Devices that are potentially more harmful are designated Class II" and may "still be marketed without advance approval," but "must comply with federal performance regulations known as 'special controls.'" *Lohr*, 518 U.S. at 477 (citing 21 U.S.C. § 360c(a)(1)(B)). This class includes such devices as powered wheelchairs and surgical drapes. *Riegel*, 552 U.S. at 316. "Finally, devices that either 'presen[t] a potential unreasonable risk of illness or injury,' or which are 'purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health,' are designated Class III." *Lohr*, 518 U.S. at 477 (citing 21 U.S.C. § 360c(a)(1)(C)). Class III medical devices include replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators. *Riegel*, 552 U.S. at 317. Essure is a Class III device.

Class III devices are subject to the highest level of scrutiny under the MDA. *Id.* "Before a new Class III device may be introduced to the market, the manufacturer must provide the FDA with a 'reasonable assurance' that the device is both safe and effective." *Lohr*, 518 U.S. at 477. The method of providing this "reasonable assurance" is known as "premarket approval" or PMA. *Id.* "Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319. (citing 21 U.S.C. § 360e(d)(6)(A)(i)). "If the applicant wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental premarket approval, to be evaluated under largely the same criteria as an initial application." *Id.* (citing 21 U.S.C. § 360e(d)(6); 21 CFR § 814.39(c)).

Express Federal Preemption

The MDA includes an express preemption provision that provides:

> no State or political subdivision of a state may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. §360k(a); *Id.* at 316. The United States Supreme Court discussed this provision at length in *Riegel v. Medtronic, Inc.* and set forth a two-step analysis for determining whether a state law claim is expressly preempted under it.[3] *Riegel*, 552 U.S. at 321-22. First, the court must determine whether the federal government established requirements applicable to the medical device. *Id.* at 321. Second, the court must determine whether the state law claim would impose requirements "different from, or in addition to," the federal requirements. *Id.* at 321-22. If both of these questions are answered in the affirmative, then the state law claim is expressly preempted. *Id.* at 321-25; *see also Zaccarello v. Medtronic, Inc.*, 38 F.Supp.3d 1061, 1066 (W.D. Mo. 2014) (stating same).

However, the Supreme Court's *Riegel* decision also specifically found that not all state law claims would be preempted under the MDA. *Riegel*, 552 U.S. at 321-22. Rather, the Supreme Court noted that the MDA's express preemption provision "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations." *Id.* at 330. In such cases, the Supreme Court concluded the state claims "'parallel,' rather than add to, federal requirements." *Id.*

[3] The only Missouri Supreme Court case to interpret the doctrine of express preemption under the MDA is the case of *Connelly v. Iolab Corp.*, 927 S.W.2d 848 (Mo. banc 1996). The Missouri Supreme Court's decision was based on its interpretation of the prior United States Supreme Court decision in *Lohr v. Medtronic Inc.*, 518 U.S. 470 (1996). However, the United States Supreme Court's *Riegel* decision, decided twelve years after both *Connelly* and *Lohr*, added considerable development to this area of the law and provided standards for determining whether preemption existed that were different from those set forth in *Lohr*. *See Riegel v. Medtronic*, Inc., 552 U.S. 312, 323-26 (2008). We are bound by the United States Supreme Court's interpretation of federal law, which includes its interpretation of the present statute. *James v. City of Boise, Idaho*, 136 S.Ct. 685, 686 (2016). Therefore, in determining whether express preemption has occurred, we will rely on the test put forth in the *Riegel* decision.

Implied Federal Preemption

In addition to expressly preempting certain state law claims, the United States Supreme Court has also found that the MDA implicitly preempts some claims. The MDA states that all actions to enforce FDA requirements "shall be by and in the name of the United States." 21 U.S.C. §337(a). The Supreme Court has held that this language means that state law based fraud-on-the-FDA claims were implicitly barred under the MDA. *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 348 (2001). In other words, "a claim that 'exist[s] solely by virtue' of federal requirements (such as a claim for fraud in submissions to the FDA during the premarket approval process) is impliedly preempted by the MDA, while claims that rely on 'traditional state tort law' may proceed (to the extent they can overcome express preemption)." *De La Paz v. Bayer Healthcare LLC*, 159 F.Supp.3d 1085, 1091–92 (N.D. Cal. 2016) (quoting *Buckman*, 531 U.S. at 349).

When the Supreme Court's decisions of *Riegel* and *Buckman* are read together, they "create a narrow gap through which a plaintiff's state-law claim must fit" in order to fully avoid preemption. *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, 623 F.3d 1200, 1204 (8th Cir. 2010) (quoting *Riley v. Cordis Corp.*, 625 F.Supp.2d 769, 777 (D. Minn. 2009). "The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *Id.* (quoting *Riley*, 625 F.Supp.2d at 777). At least one court has gone as far as comparing the difficulty of this task to navigating the treacherous passage between the mythical monsters Scylla and Charybdis. *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1340 (10th Cir. 2015). Nevertheless, J.W. asserts

that her claims against Bayer securely fit within this gap. We proceed to consider the merits of her arguments.

Count 1 – Missouri Merchandising Practices Act

In her first count, J.W. alleges that Bayer violated the MMPA by making several representations on its website concerning the Essure device that she argues were false or deceptive.[4] In order to determine if this claim is expressly preempted, we must first look to see if the FDA has established requirements applicable to Essure. In *Riegel*, the Supreme Court recognized that specifications listed in a premarket approval of a Class III medical device constituted federal requirements applicable to that device. *Riegel*, 552 U.S. at 322-23. There is no dispute in the present case that Essure is a Class III medical device that has been subject to premarket approval. Therefore, we conclude that the first step of the preemption analysis is met. We thus turn to the second step and seek to determine whether J.W.'s MMPA claim would impose requirements "different from, or in addition to," the federal requirements. *Id.* at 323.

As part of the premarket approval process, the FDA examines a device's proposed labeling to ensure that it is neither false nor misleading. *Id.* at 318. (citing 21 U.S.C. § 360e(d)(1)(A)). J.W. acknowledges this, but argues that the allegedly misleading statements were not made on the FDA's approved labeling, but rather, were listed on a website promoting the product, something that the FDA neither regulates nor reviews. While this may be true, the FDA approved labeling for Essure[5] contains a number of statements that are nearly identical to those made on the

[4] Specifically, these statements are that "Essure is the most effective permanent birth control available," Essure is "surgery free," Essure is "worry free: because your doctor will confirm that your tubes are blocked, you don't have to worry about unplanned pregnancy . . . ," Essure eliminates the risks, discomfort and recovery time associated with surgical procedures . . . ," Essure is "permanent," and Essure is made from the "same material as heart stents."

[5] For instance, the Essure Patient Information Booklet states, among other things, that Essure is "99.83% effective," the "benefits of Essure," include that it is "[n]on-[s]urgical," that "[n]o General Anesthesia [is] Required," that most women "return to normal activity within one to two days," that "Essure is a simple procedure that can be done in 10 minutes in your doctor's office," that "[a]n Essure Confirmation Test will verify that the inserts are placed correctly

Essure website of which J.W. complains. Therefore, a finding that the statements made on the Essure website were false or deceptive in violation of the MMPA would be fundamentally equivalent to finding that the FDA's approved labeling was false or deceptive. A finding that statements made in a device's labeling are misleading in violation of state law after the FDA found the statements were not misleading when it approved the labeling would ineludibly be imposing requirements "different from, or in addition to," those set forth by the FDA. *Riegel*, 552 U.S. at 323-25; s*ee also Pinsonneault v. St. Jude Medical, Inc.*, 953 F.Supp.2d 1006, 1019 (D. Minn. 2013) ("[A] claim . . . that is based on statements that a manufacturer is required to make—such as statements in an FDA-approved label—is preempted by § 360k(a) because, in order to avoid state-law liability, the manufacturer would have to do something 'which is different from, or in addition to' what federal law requires." (quoting *Riley v. Cordis Corp.*, 625 F.Supp.2d 769, 788 (D. Minn. 2009)). Thus, the second requirement for preemption is met.[6]

We note that other courts have considered claims raised on nearly identical grounds regarding the Essure device and have reached the same conclusion we reach now. *See, e.g.*, *McLaughlin v. Bayer Corporation*, No. 14-7315, No. 14-7316, No. 14-7317, No. 14-7318, No. 15-384, 2017 WL 697047, at *12 (E.D. Pa. Feb. 21, 2017) ("[T]he bulk of the alleged misrepresentations are not actionable because they are completely consistent with statements in FDA-approved materials and do not undermine—or overstate—the approved and/or required

so that you can rely on Essure for birth control," that "Essure is a permanent birth control procedure that works with your body to create a natural barrier against pregnancy," and that "these same materials have been used for many years in cardiac stents and other medical devices placed in other parts of the body." The Patient Information Booklet also gives comparisons between Essure and other methods of permanent and non-permanent contraception, each listing a higher rate of failure than Essure.

[6] We are careful to point out that this conclusion is based on the similarity between the statements included in the FDA approved label and those on the Essure website. The doctrine of express preemption does not extend to statements that go beyond those approved by the FDA, as such a claim would be premised on a *violation* of FDA regulations. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008).

statements in those materials."); *De La Paz v. Bayer Healthcare LLC*, 159 F.Supp.3d 1085, 1098 (N. D. Cal. 2016) ("Any claim . . . based on [statements approved, or even required, by the FDA] would require a determination that Essure did not conform to the descriptions approved by the FDA. Such claims are preempted."). While we acknowledge that the precedent of these courts is not binding on us, we find their rationale sound. J.W.'s claim for violation of the MMPA is expressly preempted.

Counts 2 and 3 – Fraudulent Misrepresentation and Negligent Misrepresentation

J.W.'s second and third counts are nearly identical to her first. She relies on the same statements from Bayer's promotional website for Essure and asserts Bayer knew or should have known these statements to be false. As a result, she argues that Bayer's marketing material constituted either fraudulent or negligent misrepresentations. Our analysis of these claims remains unchanged from the one set forth in the discussion of J.W.'s MMPA claim. The statements of which she complains were functionally equivalent to those in the Essure labeling approved by the FDA. To find that Bayer made fraudulent or negligent misrepresentations through the making of these statements would require a finding contrary to that reached by the FDA and would consequently impose requirements "different from, or in addition to," those set during the premarket approval process. *Riegel*, 552 U.S. at 323-25; *see also McLaughlin*, 2017 WL 697047, at *12; *De La Paz*, 159 F.Supp.3d at 1098. Therefore, J.W.'s fraudulent and negligent misrepresentation claims are both expressly preempted.

Count 4 – Breach of Express Warranties

The fourth count of J.W.'s First Amended Petition alleges that Bayer breached express warranties made to J.W. in connection with her purchase of the Essure device. However, the warranties J.W. refers to are the same statements that formed the basis for her

claims of fraudulent and negligent misrepresentation as well as her claim for violation of the MMPA. Thus, while this claim may ostensibly appear different to her first three claims, we find it to be identical and consequently reach the same result. The warranties are substantially similar to the statements included in Essure's labeling that were approved by the FDA. To hold that the Essure device did not conform to these statements would second-guess the FDA's judgment, a result that the express preemption provision of the MDA prevents.[7] *See Riegel*, 552 U.S. at 323-25; s*ee also De La Paz*, 159 F.Supp.3d at 1098. J.W.'s claim for breach of express warranties is expressly preempted.

Count 5 – Breach of Implied Warranty of Merchantability

J.W.'s fifth count alleges that the Essure device is not fit for the ordinary purpose for which it is sold (insertion into a woman's fallopian tubes to cause sterility), thus breaching the implied warranty of merchantability. Such a claim appears to be expressly preempted on its face as it directly contradicts the FDA's determination that Essure is a safe and effective means of birth control and thus would expose Bayer to liability "notwithstanding compliance with relevant federal requirements." *Riegel*, 552 U.S. at 330. J.W. seeks to avoid such a conclusion by

[7] J.W. seeks support for her claim from *Hofts v. Howmedica Osteonics Corp.*, 597 F.Supp.2d 830 (S.D. Ind. 2009). The plaintiff in *Hofts* sued the manufacturer of an artificial hip replacement device claiming that said device was negligently manufactured and had breached express warranties made to him by the manufacturer. *Id.* at 833. The manufacturer argued that the plaintiff's express warranty claims were preempted as they challenged statements made in the device's FDA approved label and package inserts. *Id.* at 839. The court rejected this argument noting that:

> [Defendant] has confused [plaintiff's] express warranty claim with a defective labeling claim, *which would be preempted under Riegel*. [Plaintiff] does not allege that the [defendant]'s FDA-approved label was defective. [Plaintiff] is perfectly happy with the label. He contends only that the device implanted in *his* hip should fit the description on that label.

Id. (emphasis added). However, J.W.'s claims in the present case are not the same as those in *Hofts*. She does not argue that the warranties made in the Essure labeling were breached because her Essure device was not manufactured in conformance with FDA requirements. Rather, she argues that the statements made by Bayer were false *ab initio*, and would have been so regardless of whether Bayer adhered to FDA requirements. A claim that the statements made in, or otherwise substantially similar to, the FDA approved labeling for a device are generally false is equivalent to a defective labeling claim, which the *Hofts* court noted would be preempted under R*iegel v. Medtronic*, Inc., 552 U.S. 312 (2008). *Id.*

arguing that numerous courts have found claims for breach of the implied warranty of merchantability are not preempted if the plaintiff alleges that the defendant violated federal requirements and can show a causal link between the violation and the breach of the implied warranty. *See Bass v. Stryker Corp.*, 669 F.3d 501, 516-17 (5th Cir. 2012). She further attempts to demonstrate that her claim meets this requirement by alleging that Bayer failed to report information concerning adverse reactions to the Essure device to the FDA as required under the MDA. However, the cases on which J.W. relies concern claims that a device manufacturer violated an MDA regulation during the *manufacturing* of a device. *See Bass*, 669 F.3d at 517 (Claim for breach of the implied warranty of merchantability because defendant "*manufactured* the [device] in violation of the FDA requirements" was not preempted. (emphasis added)); *Gelber v. Stryker Corp.*, 788 F.Supp.2d 145, 166 (S.D. N.Y. 2011) ("Plaintiffs' implied warranty claims are not preempted to the extent they allege a defective *manufacturing claim*." (emphasis added)). By contrast, J.W.'s claim alleges that Essure is *by its very nature* unfit for the ordinary purpose for which it is sold, and that, had Bayer properly reported adverse reactions to the FDA, the FDA would have recognized this and revoked its approval of the device. Such a claim is directly at odds with the express preemption provision of 21 U.S.C. §360k(a) as recognized by the United States Supreme Court in *Riegel*. *Riegel*, 552 U.S. at 324-25 (State tort law that contradicts FDA approval of a device "disrupts the federal scheme no less than state regulatory law to the same effect.").

While a claim alleging damages arising directly as a result of a medical device manufacturer's failure to adhere to MDA reporting requirements may avoid preemption, as discussed in Count six, the same is not true for a claim that would effectively revoke FDA approval of a device. Therefore, the trial court did not err in finding J.W.'s fifth claim was preempted.

Count 6 – Negligence *Per Se*

The sixth count of J.W.'s First Amended Petition is brought under a negligence *per se* theory. There are four elements to a claim of negligence *per se* under Missouri law: "(1) the defendant violated a statute or regulation; (2) the injured plaintiff was a member of the class of persons intended to be protected by the statute or regulation; (3) the injury complained of was the kind the statute or regulation was designed to prevent; and (4) the violation of the statute or regulation was the proximate cause of the injury." *Hente v. 21st Century Centennial Insurance Co.*, 467 S.W.3d 857, 864 (Mo. App. S.D. 2015) (quoting *Dibrill v. Normandy Associates, Inc.*, 383 S.W.3d 77, 84–85 (Mo. App. E.D. 2012). The gravamen of this claim is Bayer's alleged violation of the MDA and the Essure PMA through its failure to inform the FDA of reports of adverse reactions to the Essure device and by failing to provide the FDA information that the Essure device may have caused or contributed to cause serious injuries. This claim does not set forth requirements "different from, or in addition to," those set by the MDA and the Essure PMA, but rather, alleges that Bayer failed to adhere to the requirements of the MDA and the Essure PMA. Therefore, this claim is not expressly preempted. *Riegel*, 552 U.S. at 330.

Bayer argues that even if J.W.'s claim is not expressly preempted, it is still subject to implied preemption under the United States Supreme Court's *Buckman* decision. *Buckman* concerned a plaintiff who attempted to bring a state law fraud claim based on purported misrepresentations made to the FDA by a consulting firm working on behalf of a device manufacturer seeking approval for orthopedic bone screws. *Buckman*, 531 U.S. at 343. The Supreme Court held that claim was impliedly preempted because it sought to enforce an exclusively federal requirement and was not grounded in traditional state tort law. *Id.* at 352–53. Bayer now argues that J.W.'s claim is similarly based exclusively on federal requirements and

fails to invoke any traditional state law tort claim. We disagree. J.W.'s petition does not rely solely on the MDA and Essure PMA reporting requirements and instead properly invokes a traditional state law tort cause of action; specifically, a strict liability failure to warn claim. *See* Mo. Rev. Stat. § 537.760. Thus, her claim is not analogous to the "fraud-on-the-FDA" theory that was rejected in *Buckman* and is instead grounded on a well-established duty imposed on manufacturers by Missouri state law to warn consumers about the risks of using their product, which J.W. argues Bayer breached by failing to meet the post-premarket approval reporting requirements listed in the MDA and the Essure PMA.

Once again we note that several other courts have considered claims that are nearly identical to the one now being raised by J.W. and have reached conclusions consistent with our own. *See Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 775 (5th Cir. 2011) (holding state law negligence *per se* claim based on failure to adhere to FDA reporting requirements was not impliedly preempted as it asserted traditional Mississippi tort claim based on failure to warn.); *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013) (holding trial court erred in not permitting plaintiff to amend complaint to include a claim based on Arizona negligence law arising out of defendant medical device manufacturer's failure to report adverse events to the FDA). As previously noted, though these cases are not binding on us, we find their rationale persuasive.

In order to prevail on her claim, J.W. must still prove all four elements of a claim for negligence *per se* under Missouri law. This includes proving that "the violation of the statute or regulation was the proximate cause of the injury." *Hente*, 467 S.W.3d at 864 (quoting *Dibrill*, 383 S.W.3d at 84–85). Thus, J.W. will have to prove not only that Bayer failed to inform the FDA of reports regarding adverse reactions to Essure as required in the MDA and the Essure PMA, but also that, had Bayer disclosed these adverse reactions, the FDA would have taken actions which

would have better informed J.W. of the risks of the procedure and prevented the injury she alleges. *See Stengel.,* 704 F.3d at 1234 (Watford, J., concurring) ("[T]o prevail, [the plaintiff] will ultimately have to prove that if [defendant] had properly reported the adverse events to the FDA as required under federal law, that information would have reached [plaintiff]'s doctors in time to prevent his injuries."). Because the posture of the present appeal is the review of a grant of a motion to dismiss, we need not and do not address the ultimate efficacy of J.W.'s claim in Count 6; instead, we view the facts and all reasonable inferences in a light most favorable to J.W. as the non-movant. In so doing, we conclude that Count 6 states a valid cause of action that is not expressly or impliedly preempted by federal law and the trial court erred in concluding otherwise.

Counts 7 and 8 – Strict Products Liability – Defective Manufacturing and Negligent Manufacturing

J.W.'s seventh count asserts a claim for strict product liability by arguing that the Essure device implanted in her had been defectively manufactured and was thus in an unreasonably dangerous and defective condition at the time of use. Specifically, she claims that her Essure device was manufactured using "improper and nonconforming material" in violation of the Essure PMA requirements and that Bayer violated the FDA's Current Good Manufacturing Practices (CGMPs) in a number of ways with regard to the standards employed at its manufacturing facilities. J.W.'s eighth count claims that Bayer breached its duty of reasonable care in manufacturing her Essure device for the same reasons. Due to the similarity of these two counts, we consider them together.

Because the express preemption provision of the MDA prohibits States from enforcing requirements "different from, or in addition to," those approved by the FDA, J.W.'s claims may only proceed if she alleges specific manufacturing requirements imposed by the FDA that

Bayer failed to adhere to. *Riegel*, 552 U.S. at 323-25; *Norman v. Bayer Corp.*, No. 3:16-cv-00253, 2016 WL 4007547, at *3 (D. Conn. Jul. 26, 2016); *De La Paz v. Bayer Healthcare LLC*, 159 F.Supp.3d 1085, 1094 (N. D. Cal. 2016). As previously noted, the Supreme Court has found that the PMA of a Class III device imposes requirements on that device. *Riegel*, 552 U.S. at 323-24. Therefore, J.W.'s claim that her Essure device was manufactured with non-conforming material in contravention of the Essure PMA alleges the violation of a FDA imposed requirements and is consequently not expressly preempted. *See Warren v. Howmedica Osteonics Corp.*, No. 4:10 CV 1346 DDN, 2011 WL 1226975, at *3–4 (E.D. Mo. Mar. 29, 2011) (Plaintiff's claim that medical device manufacturing process did not conform to the PMA standards survived preemption). However, Bayer argues that the same does not hold true for her claims that it violated the FDA's CGMPs. It asserts that because the CGMPs are nothing more than an umbrella quality system that provides "general objectives" for all device manufacturers, they cannot be used to demonstrate a violation of specific manufacturing requirements for any particular medical device. We do not agree with this assessment. Section 360k(a) specifically preempts "*any requirement* applicable under this chapter" and we can find no reason why this provision should be read to distinguish between the device specific requirements of the PMA and the general requirements imposed by the CGMPs. *See Bausch v. Stryker Corp.*, 630 F.3d 546, 555 (7th Cir. 2010) ("[W]e do not see a sound legal basis for defendants' proposal to distinguish between general [CGMPs] requirements and "concrete, device-specific" requirements. . . . [F]ederal law is clear: for manufacturers of Class III medical devices, the . . . Current Good Manufacturing Practices adopted by the FDA under its delegated regulatory authority are legally binding requirements . . . ." (internal citations omitted)); *Howard v. Sulzer Orthopedics, Inc.*, 382 F.App'x. 436, 440 (6th Cir. 2010) (unpublished) (rejecting argument that CGMP was categorically unenforceable as being too

generic to form basis of a manufacturing-defect claim). Consequently, neither J.W.'s claim based on Bayer's alleged failure to adhere to the CGMPs, nor her claim alleging that her Essure device was manufactured with non-conforming material contrary to the Essure PMA are expressly preempted.

Having determined that J.W.'s claims are not expressly preempted, we now turn to the question of implied preemption. To escape implied preemption, J.W. must allege that Bayer's actions in violation of the Essure PMA or CGMPs were sufficient to establish a claim under Missouri law that exists independent of the federal requirements. Stated differently, she cannot simply stand on the argument that her device was not manufactured in conformance with the Essure PMA or CGMPs. *See De La Paz*, 159 F.Supp.3d at 1094-95 ("Nevertheless, to escape implied preemption [plaintiff] must allege that the irregularities documented in the Form 483s resulted in a manufacturing defect that caused her injuries. In other words, she cannot state a claim based solely on Bayer's adulteration of certain Essure devices, since any such claim would 'exist solely by virtue of the [MDA] ... requirements.'" (quoting *Buckman*, 531 U.S. at 353)).

We understand J.W.'s claims to be that Bayer's violation of the Essure PMA or CGMPs are what caused her device to break apart. A claim that the materials or methods used to manufacture a product caused it to break apart in an unintended manner when put to its reasonably anticipated use (thereby causing injury to a consumer) is sufficient to give rise to a cause of action under Missouri law independent of any federal regulation. *See* Mo. Rev. Stat. § 537.760 (2017) (setting forth elements for strict liability claim); *Morrison v. Kubota Tractor Corp.*, 891 S.W.2d 422, 425-26 (Mo. App. W.D. 1994) (setting forth elements of negligence claim for products liability). Therefore, her claims do not simply stand on the premise that her device was not manufactured in conformance with the Essure PMA or CGMPs, but go on to assert state law based

causes of action that exist independent of such violations. Read as such, her claims are not impliedly preempted under the MDA and therefore the trial court erred in finding them preempted.[8]

Count 9 – Strict Products Liability for Failure to Warn – Off-Label Use[9]

J.W.'s ninth count alleges that her physicians' attempt to remove the Essure device after it had been implanted constituted an "off-label use" of the device and that Bayer did not provide adequate warnings regarding the risks associated with this "off-label use." This claim must fail as a matter of law. The term "off-label use" refers to the "use of a device for some other purpose than that for which it has been approved by the FDA." *Buckman,* 531 U.S. at 350. It is not logical to suggest that the attempted removal of a contraceptive device meets this definition. The removal of a contraceptive device is not an attempt to use it for "some other purpose" but rather seeks to eliminate its purpose. Thus, the removal of the Essure device implanted in J.W. cannot be considered a "use" of that device, off-label or otherwise. Because we conclude, as a matter of law, that the attempt to remove the Essure device did not constitute an "off-label use" of the device, we find that J.W.'s ninth count fails to state a claim upon which relief can be granted. We therefore need not reach the question of preemption.

[8] In order to ultimately prevail on either claim, J.W. will have to establish not only that her particular device was manufactured in violation of the Essure PMA or CGMPs but also that it was this violation that caused it to break apart. Anything less would be venturing into the realm of preemption as it would amount to a finding either that her Essure device was in a dangerous defective condition or negligently manufactured for some reason *other than* a violation of the MDA or else that it was in a dangerous defective condition or negligently manufactured *solely because* it violated the MDA. The first of these outcomes is expressly preempted, the second is subject to implied preemption. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008); *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 354–55 (2001). Further, these requirements stand in addition to the elements already set forth in statute and the common law.

[9] There is some confusion as to whether this count was voluntarily dismissed by J.W.. There was a colloquy with the trial court where counsel for J.W. indicated an intention to dismiss this count. The trial court informed counsel to "file whatever you're going to file, and we'll go from there." It does not appear to this Court that J.W. ever filed that voluntary dismissal and we note that the trial court did address the claim in its judgment and dismissed it on preemption grounds. As a result, we consider it properly before this Court and address it accordingly.

Count 10 – Failure to Warn — Post PMA Risks

J.W.'s tenth count claims that Bayer failed to either provide additional warnings in the Essure labeling or else remove Essure from the market after receiving reports regarding adverse side effects it had allegedly received after the device was granted premarket approval. This claim is expressly preempted because there is no parallel requirement under the MDA for a device manufacturer to either include additional warnings for potential users or else remove a device from the market due to adverse side effects discovered after receiving premarket approval, meaning J.W.'s claim would necessarily impose requirements "different than, or in addition to," those set by the MDA.[10] *Riegel*, 552 U.S. at 323-25; *see also In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, 623 F.3d 1200, 1205 (8th Cir. 2010) ("Plaintiffs did not allege that [defendant] modified or failed to include FDA-approved warnings. Rather, they alleged that, by reason of state law, [defendant] was required to give additional warnings, precisely the type of state requirement that is 'different from or in addition to' the federal requirement and therefore preempted."); *Gomez v. St. Jude Medical Daig Div. Inc.*, 442 F.3d 919, 932 (5th Cir. 2006) ("[Plaintiff]'s state-law claims related to [defendant]'s alleged failure to provide information obtained after the FDA approved the [medical device] risk the same interference with the federal regulatory scheme as her other claims and are preempted.").

[10] J.W.'s seeks to avoid this conclusion by pointing to a general FDCA requirement that a device manufacturer not sell "misbranded" devices. She argues that the newly reported side effects of Essure rendered its labeling false and misleading and thus "misbranded." In essence, she argues that Bayer violated general FDCA labeling requirements despite the fact that it sold Essure with the approved PMA labeling. We consider this argument nothing more than a basic mislabeling claim, the kind that is expressly preempted under the United States Supreme Court's decision in *Riegel*. The extent to which post-premarket approval discoveries regarding Essure rendered its PMA labeling invalid is a question that 21 U.S.C. §360k(a) and 21 U.S.C. §337(a) have placed exclusively in the hands of the FDA. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 325-30 (2008); *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 347-51 (2001); see also *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1234 (9th Cir. 2013) (Watford, J., concurring) (noting that a direct "failure to warn" claim based on post-premarket approval discoveries is expressly preempted under 21 U.S.C. § 360k but acknowledging that a negligence claim based on a device manufacturer's failure to adhere to MDA reporting requirements regarding the same post-premarket approval discoveries is not).

Count 11 – Negligent Training

The eleventh count in J.W.'s First Amended Petition claims that Bayer was negligent in training her treating physicians regarding the proper use of the Essure device and related hysteroscopic equipment used during the placement of the device. She argues that Bayer voluntarily undertook to train her physicians, thus creating a common law duty that existed independent of the protections afforded by the Essure PMA. Bayer responds by alleging that the FDA specifically approved Essure's physician training requirements as part of the PMA process and that J.W.'s claims are expressly preempted in light of those approved training requirements. We agree with Bayer's arguments in as far as they relate to claims that it failed to provide training beyond what was approved during the PMA process and set forth in the Essure labeling.[11] Such claims would be establishing requirements that were "different from, or in addition to," those set by the Essure PMA, and would thus be expressly preempted. *See Riegel*, 552 U.S. at 323-25. However, the same would not hold true for claims that Bayer failed to adhere to the FDA requirements in performing whatever training it did provide. Such a claim does not add any different or additional requirements, but rather, raises a claim that parallels the federal requirements. *See Riegel*, 552 U.S. at 330; *McLaughlin v. Bayer Corporation*, 172 F.Supp.3d 804, 816 (E.D. Pa. 2016) ("[W]e conclude that, at least to the extent that the [negligent training] claim alleges that Bayer failed to abide by FDA-approved training violations [sic], the negligent training claim does not seek to impose training requirements different from those in the federal requirements and, thus, is not expressly preempted on that basis but, rather, asserts a permissible parallel claim."). We therefore proceed to examine the claims of alleged breach raised in J.W.'s First Amended Petition to determine if they assert Bayer failed to train J.W.'s

[11] A Class III medical device which is subject to specific training requirements must set forth said requirements on its labeling. 21 USCA § 360j(e)(2).

physicians in a manner consistent with the FDA requirements, and thus avoid express preemption, or if they contend failure to train beyond those requirements and are consequently preempted.

J.W.'s petition alleges that Bayer breached the duty it owed to train J.W.'s physicians in three ways. First, J.W. alleges that Bayer negligently provided training to her physicians regarding the placement of the Essure micro-inserts and that the training it gave was different from that required by the FDA approved "Physician's Training Manual." Because this alleged breach claims the training provided by Bayer deviated from the FDA approved training manual, it is not expressly preempted. *See Riegel*, 552 U.S. at 530; *McLaughlin*, 172 F.Supp.3d at 816. Nor is this claim impliedly preempted as Missouri law recognizes that, in certain situations, a party who undertakes to perform services, such as Bayer undertaking to train J.W.'s physicians, may be subject to liability to a third party for failing to exercise due care in rendering those services. *Junior C. Dist. of St. Louis v. City Of St. Louis*, 149 S.W.3d 442, 451 (Mo. banc 2004). Thus, J.W. may proceed on her claim that Bayer trained her treating Physicians in a manner that went beyond the scope of the FDA approved training manual, failed to exercise due care in doing so and, as a result, she was damaged.[12]

Next, J.W. argues that Bayer breached its duty to properly train her physicians by failing to supervise her placement procedure. Unlike the previously asserted breach, this argument does not arise out of training Bayer allegedly provided, but instead asserts Bayer was negligent for *failing* to train J.W.'s treating physicians on matters beyond what the FDA required. Nothing

[12] In order to prevail on this claim, J.W. must show both that Bayer affirmatively trained her treating physicians in a manner that was different from the requirements of the "Physician's Training Manual" and that it breached the duty of reasonable care owed to her while it was doing so. Without the former, her claim is expressly preempted, as there is no longer a violation of FDA regulation on which a parallel state claim may be based. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008). Meanwhile, failure to show the latter would risk implied preemption as it would be attempting to state a claim based *solely* on deviation from FDA regulations. *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 354–55 (2001).

in the FDA approved training requirements necessitates that each placement procedure be supervised by Bayer. Therefore this claim would effectively add a requirement that was "different than, or in addition to," those set by the FDA and is thus expressly preempted. *Riegel,* 552 U.S. at 323-25.

Finally, J.W. contends that Bayer breached its duty by failing to train her physicians in the use of the hysteroscopic equipment it supplied to them. Much as with the asserted breach for failure to supervise, this claim rests not on the training Bayer provided but on what J.W. alleges Bayer *failed* to provide. Further, while the FDA approved training requirements do caution that the device is only to be used by knowledgeable hysterocopists, we find nothing to suggest that Bayer was the one required to provide such training. *McLaughlin,* 172 F.Supp.3d at 818 n. 9 ("[U]nlike Plaintiffs, we cannot discern [a requirement to train physicians in hysteroscopy when providing them with hysteroscopic equipment] in the FDA's mandated warning label for Essure, which simply cautions that Essure is only to be used by knowledgeable hysterocopists."). To therefore place upon Bayer a duty to provide this training would be imposing a requirement "different than, or in addition to," what is required by the FDA and is consequently expressly preempted. *See id.; Riegel,* 552 U.S. at 323-25.

The trial court did not err in finding J.W.'s eleventh count was expressly preempted to the extent that she alleges a breach of the duty to train based on a failure to supervise her placement procedure and a failure to train her treating physicians to use the hysteroscopic equipment supplied by Bayer. The trial court did err in finding J.W.'s eleventh count was preempted to the extent that she claims Bayer failed to use reasonable care when training her physicians in a manner different from what was approved by the FDA as set forth in the "Physician's Training Manual."

Count 12 – Negligently Supplying a Product for Use

In count twelve, J.W. claims that Bayer negligently supplied J.W.'s physicians with defective surgical equipment, such as hysteroscopes,[13] for use in inserting the Essure device. Unfortunately, it is unclear from J.W.'s petition the extent to which the surgical devices she now alleges to be defective would be considered entirely separate from the Essure device or instead were a component of the Essure system. A claim that surgical equipment that is part of the Essure system — and consequently reviewed and approved through the Essure PMA process — was defective would be preempted because it would impose requirements "different from, or in addition to," those set by the FDA. *See Riegel*, 552 U.S. at 323-25. By contrast, a claim that Bayer provided defective ancillary surgical implements to assist with the insertion of the Essure device which were *not* reviewed and approved by the FDA during the pre-market approval of Essure would not be preempted based on the Essure PMA because the claim would not modify or add to the requirements established by the FDA through the Essure approval process. Therefore, we find that the trial court erred in concluding J.W.'s claim is fully preempted and she may proceed with her claim to the extent that it relates to surgical instruments that did not receive FDA approval as part of the Essure PMA.[14]

Count 16 – Civil Conspiracy

The sixteenth count raised in J.W.'s First Amended Petition alleges a claim for civil conspiracy against all of the named defendants incorporating all of the previously discussed

[13] A hysteroscope is an endoscope used in direct visual examination of the canal of the uterine cervix and cavity of the uterus. *Hysteroscope*, MOSBY'S MEDICAL DICTIONARY (7th ed. 2006).

[14] We do not address whether the surgical equipment that did not undergo review as part of the Essure PMA are themselves medical devices subject to regulation under the MDA, which might give rise to preemption independent of the regulation on the Essure device. Such considerations are beyond the scope of our review given that the parties have raised no arguments concerning this issue either before the trial court or on appeal.

counts. Missouri law defines a civil conspiracy as "an agreement between at least two persons to do an unlawful act, or to use unlawful means to do an act which is lawful." *Hibbs v. Berger*, 430 S.W.3d 296, 320 (Mo. App. E.D. 2014) (quoting *Blaine v. J.E. Jones Constr. Co.*, 841 S.W.2d 703, 713 (Mo. App. E.D. 1992)). The tort of civil conspiracy does not exist in its own right; "[r]ather, it acts to hold the conspirators jointly and severally liable for the underlying act." *Western Blue Print Co., LLC v. Roberts*, 367 S.W.3d 7, 22 (Mo. banc 2012) (quoting *8000 Maryland, LLC v. Huntleigh Fin. Services Inc.*, 292 S.W.3d 439, 451 (Mo. App. E.D. 2009)). "The gist of the action is not the conspiracy, but the wrong done by acts in furtherance of the conspiracy or concerted design resulting in damage to plaintiff." *Id.* (quoting *8000 Maryland*, 292 S.W.3d at 451). Therefore, if the "tortious acts alleged as elements of a civil conspiracy claim fail to state a cause of action, then the conspiracy claim fails as well." *Id.* (quoting *Oak Bluff Partners, Inc. v. Meyer*, 3 S.W.3d 777, 781 (Mo. banc 1999)).

We presume the trial court found this claim to be preempted owing to the fact that it found all of J.W.'s previous claims directed against Bayer to be preempted. *See, e.g., Timberlake v. Synthes Spine, Inc.*, No. V-08-4, 2011 WL 711075, at *11 (S.D. Tex. Feb. 18, 2011) ("Because the Court has determined that all of [plaintiff]'s other claims are preempted or otherwise factually deficient, his claim for civil conspiracy must fail for lack of an underlying claim to support it."). *Hibbs*, 430 S.W.3d at 320. (dismissing civil conspiracy after affirming trial court's grant of summary judgment on the underlying tort claim). Therefore, to the extent that we have determined that the trial court erred in finding several of J.W.'s claims were preempted, it has also erred in finding this claim was preempted. J.W.'s civil conspiracy claim may proceed as to any of the previous claims that we have found not to be preempted.

Count 17 – *Res Ipsa Loquitur*

J.W.'s seventeenth count raises a general negligence claim that relies on the doctrine of *res ipsa loquitur*. "The doctrine of *res ipsa loquitur* is 'a rule of evidence that permits a jury to infer from circumstantial evidence that the defendant is negligent without requiring that the plaintiff prove defendant's specific negligence.'" *State ex rel. GS Tech. Operating Co., Inc. v. Public Service Commission of State of Mo.*, 116 S.W.3d 680, 694 (Mo. App. W.D. 2003) (quoting *Weaks v. Rupp*, 966 S.W.2d 387, 393 (Mo. App. W.D. 1998)). This presents an obvious problem for J.W.. Because of the general nature of the doctrine of *res ipsa loquitur*, a fact finder could rule in favor of J.W. without finding that Bayer violated any federal regulation. Such a finding would impose requirements "different from, or in addition to," those in the Essure PMA and would thus be expressly preempted. *See Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011) ("[Plaintiff] provides no facts in support of his conclusory allegations, instead relying on the doctrine of *res ipsa loquitur*—a doctrine that would seem to be soundly refuted by *Riegel*. (internal citation omitted)); *Estate of LeMay v. Eli Lily & Co.*, 960 F.Supp. 183, 186 (E.D. Wis. 1997) ("The MDA . . . allows a negligence action to proceed only for violations of the FDA regulations. Because *res ipsa loquitur* could allow recovery for negligence that Congress has preempted, the [plaintiffs] may not rely on the doctrine.").

J.W. seeks to address this problem by arguing that use of the doctrine of *res ipsa loquitur* should still be permitted if it can be demonstrated that the events in question only occur because of wrongful conduct not insulated by preemption (*i.e.* manufacturing that violates MDA requirements). We need not determine the validity of this argument however, as we find that J.W.'s petition does not allege facts to support such a conclusion. Nothing in J.W.'s petition can be read as arguing that her injuries could only have arisen as a result of a MDA

requirement violation. On the contrary, the FDA approved labeling for Essure indicated that part of it may break off during insertion and that it might puncture the fallopian tubes, which means that breakage of the Essure device is clearly considered a potential risk even when manufactured correctly. Thus, *res ipsa loquitur* is inapplicable regardless of whether we were to accept J.W.'s argument. J.W.'s seventeenth count is expressly preempted.

Denial of J.W.'s Request for Leave to Amend her Petition

J.W. responded to the trial court's granting of Bayer's Motion to Dismiss by filing a Motion to Amend Judgment and request for leave to file a Second Amended Petition. In her second point raised on appeal, J.W. argues that the trial court erred in not granting the request for leave to amend her petition included in the Motion to Amend Judgment.

"The trial court is vested with broad discretion to grant leave to amend the pleadings at any stage of the proceedings." *Robinson v. City of Kansas City*, 451 S.W.3d 315, 319 (Mo. App. W.D. 2014) (quoting *Johnson v. Allstate Indem. Co.*, 278 S.W.3d 228, 237 (Mo. App. E.D. 2009)). We will therefore not overturn a trial court's decision not to grant leave to amend a petition absent a showing that the trial court abused its discretion. *Id.* A trial court will not be found to have abused its discretion unless its ruling "is clearly against the logic of the circumstances and is so arbitrary and unreasonable as to shock the sense of justice and indicate a lack of careful consideration." *Nelson v. State*, 521 S.W.3d 229, 234–35 (Mo. banc 2017) (quoting *Murrell v. State*, 215 S.W.3d 96, 109 (Mo. banc 2007).

Because we have determined that the trial court erred in finding J.W.'s sixth, seventh, eighth, and twelfth counts, as well as portions of her eleventh and sixteenth counts, were preempted by federal law, we need not address her contention that the trial court abused its discretion in not permitting her to amend these claims. *See Martin v. City of Washington*, 848 S.W.2d 487, 491

(Mo. banc 1993) ("The judgment dismissing plaintiffs' claims against the City is reversed and that cause is remanded to the trial court for further proceedings. This determination makes it unnecessary to consider plaintiffs' contention that the trial court should have allowed them the opportunity to amend their petition . . . ."); *Dibrill v. Normandy Associates, Inc.*, 383 S.W.3d 77, 91 (Mo. App. E.D. 2012) (declining to address trial court's refusal to allow amendment of claims found to have been erroneously dismissed.).

In addition, a careful review of J.W.'s proposed Second Amended Petition reveals that the amended allegations would not have cured the preemption issues related to her remaining claims. Therefore, we need not further address the trial court's refusal to grant J.W. leave to file the Second Amended Petition as she suffered no prejudice from the trial court's action. *See, e.g., Bratt v. Cohn*, 969 S.W.2d 277, 284 (Mo. App. W.D. 1998) (denial of plaintiffs' motion to file second amended petition was not an abuse of discretion because it "did not cure the deficiencies of their first amended petition."). J.W.'s second point is therefore denied.

Conclusion

The judgment of the trial court is affirmed with regard to the dismissal of counts one, two, three, four, five, nine, ten, and seventeen of J.W.'s First Amended Petition, as well as the denial of J.W.'s request for leave to file a Second Amended Petition. The judgment of the trial court is further affirmed with regard to count eleven, only to the extent that it alleges breach of duty to train based on a failure to supervise J.W.'s placement procedure and failure to train her treating physicians to use the hysteroscopy equipment supplied by Bayer, and count sixteen to the extent that it alleges a civil conspiracy based on any of the aforementioned preempted claims as the underlying unlawful act. The trial court's decision with regard to J.W.'s sixth, seventh,

eighth, and twelfth counts, as well as the remaining portion of her eleventh and sixteenth counts, are reversed and the case is remanded for further proceedings consistent with this opinion.

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EDWARD R. ARDINI, JR., JUDGE

All concur.